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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,983	04/08/2004	Lawrence Steinman	690068.412C4	9886

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/820,983

Applicant(s)

STEINMAN ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20040709.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. The Sequence Listing filed April 8, 2004 has been approved.
2. The disclosure is objected to because of the following informalities: At page 1, line 5, the status of parent application 10/270,707 should be updated. At page 1, line 9, the filing date of the patent application should be inserted. At page 6, line 25, the SEQ ID NO should be inserted. At page 18, line 28, "rates" should be changed to "rats". Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to peptides, compositions comprising the peptides, and methods of using the peptides, in which the peptides are derived from residues 87-99 of hMBP in which at least the lysine residue at position 91 is altered to another amino acid. Accordingly, the claims recite peptides of any size greater than one amino acid, because the "derived from" language does not exclude the presence of additional amino acids and permits the deletion of any number of amino acids (except that one amino acid other than L-lysine must still be present at a position corresponding to position 91 of hMBP). The claims recite peptides having any sequence, as long as one amino acid is present which is not L-lysine, because the "at least" language at claim 1, line 2, permits alteration of other amino acids in addition to the one at a

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position corresponding to position 91 of hMBP. Of the peptides which are recited in the claims, which are unlimited with respect to length and are essentially unlimited with respect to sequence, Applicants disclose ten examples (see, e.g., Figure 3), each of which has the same length and the same sequence except for the amino acid at the position corresponding to position 91 of hMBP. Applicants do not describe any structural features necessary for the peptide analogues to bind to MHC or for the peptide analogues to be useful for treating multiple sclerosis. In view of the large genus of peptides recited in the claims, the limited number of specific peptides described in the specification, and the lack of any described correlation between the structure of the peptides and their function in binding to MHC and treating multiple sclerosis, one skilled in the art would not recognize that Applicants had within their possession the entire claimed genus of peptides, and the claims thus lack an adequate written description.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,740,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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claims of the '638 patent anticipate the instant claims. Note that a composition comprising a compound anticipates claims drawn to the compound per se.

6. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,489,299. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4 of the '299 patent anticipate instant claims 1-6. Note that a composition comprising a compound anticipates claims drawn to the compound per se. With respect to instant claims 7-11, it would have been obvious to one of ordinary skill in the art to use the composition claimed in the '299 patent in accordance with its claimed intended use.

7. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,369,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '033 patent anticipate the instant claims. Note that a method of using a compound, including the alanine analogue of claim 7 of the '033 patent, anticipates claims drawn to a method.

8. Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,329,499. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '499 patent anticipate the instant claims.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by the Martin et al article (J. Immunology, Vol. 148, pages 1359-1366). The Martin et al article teaches peptides comprising residues 88-100 of human myelin basic protein with the lysine at residue 91 altered to be Ala. The peptides are synthesized by solid phase synthesis. See, e.g., page 1360, column 1, fourth full paragraph, and Figure 3, peptide Ala5. Note that because of a different numbering system, the Martin et al article's residues 88-100 correspond to the same fragment of MBP as Applicants' residues 87-99. With respect to instant claim 5, because of the identity in amino acid sequence between the peptide of the Martin et al article and Applicants' claimed peptide analogues, inherently the peptide of the Martin et al article will reduce the expression of TNF- $\alpha$  from MBP-reactive T cells relative to the native sequence of MBP to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of the Martin et al article and Applicants' claimed peptide analogues to shift the burden to Applicants to provide evidence that the claimed peptide analogues are unobviously different than those of the Martin et al article. Because the peptides of the Martin et al article were used in in vitro cell cultures, inherently they must have been combined with a physiologically acceptable carrier or diluent.

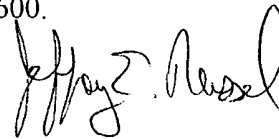
10. The two terminal disclaimers filed April 8, 2004 were not approved because they did not sufficiently identify this application in which the disclaimers were filed. The "Application No." line for each disclaimer was left blank.

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11. The references crossed off of the Information Disclosure Statement filed July 9, 2004 are duplicate citations.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

September 1, 2004